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Commissioner for Patents, P.O. Box 1450, Alexandria,  
Virginia 22313-1450, on November 10, 2006

Kathy Ashton

Name

Kathy Ashton

Signature

November 10, 2006

Date of Signature

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Egilmez

Examiner: Brandon J. Fetterolf

Filed: December 30, 2003

Art Unit: 1642

Serial No.: 10/748,003

For: Method for Inhibiting the Growth of Gastrointestinal Tract Tumors

### 37 C.F.R. 1.132 Declaration

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

I, Richard B. Bankert, declare:

1. That I am a Professor of Microbiology at the State University of New York at Buffalo School of Medicine and Biomedical Sciences; and the President and a Director of Therapyx, Inc., and that I have been conducting research on the effects of local and sustained release of pro-inflammatory agents on tumor-associated lymphocytes in the microenvironment of human cancers.

2. That I understand that the above-referenced patent application recites claims directed to a method for inhibiting the growth of gastrointestinal (GI) tumors by oral administration of IL-12 and sulindac, and that these claims have been rejected based on prior art which describes the effect of IL-12 alone or sulindac alone in reducing the growth of GI tumors. As a researcher in the field of immunotherapy of human cancer, it is my opinion that because sulindac is an anti-inflammatory agent and IL-12 is a pro-inflammatory agent, the combination of the two would not typically be considered as a therapeutic approach because

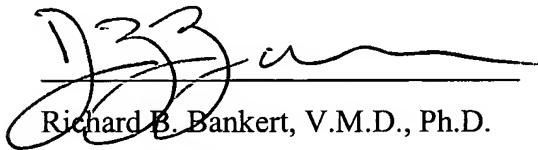
it would be expected that the effects of the two would cancel out. Therefore, in my opinion, the finding in the above application that the anti-tumor effect of the combination of IL-12 and sulindac is greater than the effect of either one alone, is surprising.

3. That all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 101 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued there from.

Respectfully submitted,

10/23/06

Date

A handwritten signature in black ink, appearing to read "R.B.Bankert, V.M.D., Ph.D." The signature is fluid and cursive, with "R.B.Bankert" in a larger, more formal script and "V.M.D., Ph.D." in a smaller, more stylized script to the right.